



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Lower Limb Orthoses and Shoes

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

Coverage for lower limb orthotic devices is subject to the terms, conditions and limitations of the applicable benefit plan's External Prosthetic Appliances and Devices (EPA) or Durable Medical Equipment (DME) benefit and schedule of copayments. Repair and/or replacement of orthotic devices may also be limited under some benefit plans. Under many benefit plans, coverage for EPA and DME is limited to the lowest-cost alternative.

Under many benefit plans formerly administered by Great-West Healthcare, orthotics are only covered when they are custom-designed, prescribed by a doctor and required for all normal, daily activities.

In addition, some benefit plans may specifically exclude or limit coverage for certain orthotic devices and shoes. Many benefit plans specifically exclude coverage for the following orthoses and orthotic devices (this list may not be all-inclusive):

- prefabricated (including custom-fitted) foot orthoses
- orthotic shoes, shoe additions, procedures for foot orthopedic shoes, shoe modifications and transfers
- orthoses primarily used for cosmetic reasons
- orthoses primarily for improved athletic performance or sports participation

- corrective orthopedic shoes
- arch supports

Please refer to the applicable benefit plan document and schedules to determine benefit availability and the terms, conditions and limitations of coverage.

A prefabricated orthosis is any orthosis manufactured in quantity without a specific individual in mind (e.g., off-the-shelf). Prefabricated orthotic devices may include custom-fitted devices (e.g., trimmed, bent or molded for use by a specific individual).

A custom-fabricated orthosis is one that is specifically manufactured for an individual. Custom-fabricated devices may include custom-molded devices (e.g., molded to the individual's specific body part).

If coverage is available, the following lower limb orthotic devices may be covered when medical necessity is established:

- custom-fabricated foot orthoses
- the following non-foot lower limb orthoses:
 - rigid and semi-rigid custom-fabricated orthoses
 - semi-rigid prefabricated and flexible orthoses
 - rigid prefabricated orthoses, including preparation, fitting and basic additions such as bars and joints

FOOT ORTHOSES

CIGNA covers a custom-fabricated foot orthosis as medically necessary when there is failure, contraindication, or intolerance to a prefabricated foot orthosis for ANY of the following conditions:

- individuals with impaired peripheral sensation and/or altered peripheral circulation (e.g., diabetic neuropathy and peripheral vascular disease)
- the foot orthosis is an integral part of a leg brace and is necessary for the proper functioning of the brace
- the foot orthosis is used to compensate for a missing portion of the foot (e.g., amputation) and is necessary for the alleviation or correction of illness, injury or congenital defect
- individuals with neurologic or neuromuscular conditions (e.g., cerebral palsy, hemiplegia, spina bifida) producing spasticity, malalignment or pathological positioning of the foot where there is reasonable expectation of improvement
- for the treatment of plantar fasciitis, following failure of conservative medical management (e.g., stretching/strengthening of calf muscles, taping, strapping, nonsteroidal anti-inflammatory medications, reduced activity and physical therapy) including, unless contraindicated, at least a six-week trial of a prefabricated or custom-fitted orthosis
- individuals with acquired or congenital foot deformities when ALL of the following criteria are met:
 - The deformity is the result of ONE of the following:
 - symptomatic rigid flatfoot
 - posterior tibial tendon dysfunction
 - mid- or hind-foot arthritis
 - The deformity is associated with significant pain that interferes with activities of daily living and there is impaired gait, balance or mobility as a result of the condition.
 - Conservative medical management has failed.
 - There is a reasonable expectation that the condition will improve through the use of the orthotic device.

ANKLE/FOOT/KNEE ORTHOSES

CIGNA will cover a custom-fitted lower limb orthosis if there is failure, contraindication, or intolerance to an unmodified, prefabricated orthotic device.

CIGNA will cover a custom-fabricated lower limb orthosis if there is failure, contraindication, or intolerance to a custom-fitted orthotic device.

CIGNA covers an ankle orthosis as medically necessary for ANY of the following indications:

- ankle fractures
- ankle sprains
- ankle injuries requiring immobilization and/or stabilization

CIGNA covers a basic ankle-foot orthoses (AFO) and knee-ankle-foot orthosis (KAFO) (ankle contracture splint or foot drop splint) as medically necessary in a NON-AMBULATORY individual who meets ALL of the following criteria:

- The individual has a plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a non-fixed contracture).
- There is reasonable expectation of the ability to correct the contracture.
- The contracture is interfering or expected to interfere significantly with the person's functional abilities.
- The ankle contracture splint is used as a component of a therapy program that includes active stretching of the involved muscles and/or tendons.

CIGNA covers ANY of the following orthoses as medically necessary in an AMBULATORY individual:

- an ankle-foot orthosis (AFO) in an individual with a weakness or deformity of the foot and ankle requiring stabilization who is expected to have improved function with the use of the device
- a knee-ankle-foot orthosis (KAFO) in an AMBULATORY individual who meets criteria for ankle-foot orthoses and who requires additional knee stability
- a molded-to-individual model AFO and KAFO in an AMBULATORY individual who meets criteria for an AFO or KAFO and ANY ONE of the following applies:
 - The individual cannot be fitted with a prefabricated (off-the-shelf) AFO or has a documented neurological, circulatory or orthopedic status that necessitates custom fabrication to prevent tissue injury.
 - The condition necessitating the orthosis is expected to be permanent or of long-standing duration (> 6 months).
 - There is a need to control movement about the knee, ankle or foot in more than one plane.
 - The individual has a healing fracture that lacks normal anatomical integrity or anthropometric proportions.

SHOES

Corrective orthopedic shoes, orthosis shoes, shoe additions, procedures for fitting orthopedic shoes, shoe modifications and transfers are specifically excluded under many benefit plans. If coverage is available for shoes, the following conditions of coverage apply-

CIGNA covers depth shoes (including inlays provided with the shoe) as medically necessary for individuals with ANY of the following systemic conditions, that are significant enough to result in severe circulatory insufficiency and/or areas of decreased peripheral sensation in the lower extremity (This list may not be all-inclusive):

- diabetes mellitus
- peripheral vascular disease
- peripheral neuropathy

CIGNA covers custom molded shoes (including inlays provided with the shoe) as medically necessary when criteria have been met for a depth shoe, and the type and/or severity of foot deformity results in failure, contraindication or intolerance to a depth shoe.

CIGNA covers ANY of the following modifications to medically necessary depth or custom-molded shoes (This list may not be all inclusive):

- rigid rocker bottoms
- roller bottoms
- wedges
- metatarsal bars
- offset heels

NOT COVERED

CIGNA does not cover ANY of the following lower limb orthoses or orthotic devices, as they are considered not medically necessary:

- separate orthotic devices for an additional pair of shoes
- orthoses used on uninjured body parts or to prevent injury
- orthoses used to treat edema
- orthoses used to treat pressure ulcers
- socks used in conjunction with orthoses
- ankle contracture and foot drop splints used as recumbent positioning devices
- orthoses primarily for improved athletic performance or sports participation
- deluxe features for therapeutic shoes (e.g., special colors, type of leather, style)
- inlays/inserts that are direct-formed, compression molded to the individual's foot without the use of an external heat source

CIGNA does not cover ANY of the following orthoses because they are considered experimental, investigational or unproven (this list may not be all-inclusive):

- custom-fabricated foot orthoses for the treatment of hallux valgus or hallux rigidus foot deformity
- magnetic insoles (i.e., orthoses with magnetic foil)
- stance control orthoses

REPAIR/REPLACEMENT

CIGNA covers repair and/or replacement of a lower limb orthosis under the following circumstances:

- Repair is covered only when anatomical change or reasonable wear and tear renders the item nonfunctional and the repair will make the equipment usable.
- Replacement is covered only when anatomical change or reasonable wear and tear renders the item nonfunctional and nonrepairable.

CIGNA does not cover repair or replacement if the item becomes unusable or non-functioning because of individual misuse, abuse or neglect.

General Background

Orthoses are devices added to the body to stabilize or immobilize a body part, prevent deformity, protect against injury or to assist with function. Static orthoses are rigid and are used to support weakened or paralyzed body parts in a particular position. Dynamic orthoses are used to facilitate body motion to allow optimal function.

Lower limb orthoses can be classified by anatomic location (e.g., foot orthoses, ankle orthoses, ankle-foot orthoses [AFO], knee-ankle-foot orthoses [KAFO]). The term "foot orthoses" typically refers to devices that are placed into shoes. Ankle orthoses are supportive devices used to provide immobilization to the ankle. AFOs have a shoe insert component as well as an ankle component. KAFOs contain a knee component, ankle component and shoe insert.

A splint is defined as an appliance for preventing movement of joints or for the fixation of a displaced or movable part.

A brace is defined as an orthosis or orthopedic appliance that supports or holds in correct position any movable part of the body and that allows for motion of that part. It must be a rigid or semirigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce on the limb on which it is being used.

A prefabricated orthosis is any orthoses that is manufactured in quantity without a specific patient in mind. A prefabricated orthosis can be modified (e.g., trimmed, bent or molded) for use by a specific patient and is then considered a custom-fitted orthosis. An orthosis that is made from prefabricated components is considered a prefabricated orthosis. Any orthosis that does not meet the standard definition of custom-fabricated is considered to be a prefabricated device. HCPCS codes representing prefabricated orthoses are L1902, L1906, L1910, L1930, L1951, L1971, L2035, L2112–L2116, L2036–L2108 and L2126–L2128.

A custom-fabricated orthosis is one that is specifically made for an individual patient starting with the most basic materials that may include plastic, metals, leather or various cloths. The construction of these devices requires substantial labor such as cutting, bending, molding and sewing, and may even involve the use of some prefabricated components. A molded-to-patient model orthosis is a type of custom-fabricated device for which an impression of the specific body part is made (e.g., by means of a plaster cast, or computer-aided design/computer-aided manufacturing [CAD-CAM] technology). The impression is then used to make a specific patient model. The actual orthosis is molded from the patient-specific model. HCPCS codes representing custom-fabricated orthoses are L1900, L1904, L1907, L1940–L1950, L1960–L1970, L1980–L2030, L2036–L2108 and L2126–L2128. HCPCS codes L3000–L3020 are molded to patient models and are custom-fabricated devices. The orthosis represented by HCPCS code L3030 is not molded from a model of the patient's foot but formed directly from the patient's foot without a model, and is also a custom-fabricated device.

An unmodified, prefabricated orthosis is generally used in treating a condition prior to a custom-fitted orthosis (prefabricated orthosis that is modified by bending or molding for a specific patient). A custom-fitted orthosis is generally attempted prior to the use of a custom-fabricated orthosis (individually constructed from materials).

U.S. Food and Drug Administration (FDA): A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, correct, or prevent deformities or to align body structures for functional improvement and are regulated by the FDA as Class I devices. Class I devices are subject to the least regulatory control.

Foot Orthoses

A foot orthosis is a type of shoe insert that does not extend beyond the ankle and may include heel wedges and arch supports. The goal of treating conditions with foot orthoses is to decrease pain and increase function. They may also correct some foot deformities and provide shock absorption to the foot. Foot orthoses may be used to treat conditions such as those involving impaired peripheral circulation and sensation, when they are attached to a prosthetic shoe or brace, for a neurologic or neuromuscular condition and for congenital or acquired foot conditions. HCPCS codes representing foot orthoses provided to patients without diabetes are L3000–L3090.

Conditions with Impaired Peripheral Circulation and Sensation: The major foot-related conditions that increase the risk of ulcers and amputations in those with diabetes and other conditions that impair peripheral circulation are peripheral neuropathy, altered biomechanics (caused by increased plantar pressure, bony deformities, limited joint mobility), peripheral vascular disease, skin pathology and a history of prior ulcers. When properly fitted, footwear can reduce abnormal pressures, reduce formation of calluses and ulcers and protect the foot from external trauma. Most patients with these conditions can safely wear properly-fitted commercial shoes. Prefabricated shoe inserts may also be used. The use of custom-fitted or custom-molded orthotic inserts are typically reserved for those patients with neuropathy and/or altered circulation who also have severe foot deformities such as Charcot arthropathy, severe arthritis, large bunions or prior amputation.

Foot Orthoses Associated with Prosthetic Shoes and Braces: Prosthetic shoes are used when all or a portion of the foot is missing. A brace may or may not be attached to the prosthetic shoe. The absence of all or a portion of the foot may be the result of a congenital deformity, illness (amputation secondary to diabetic foot ulcer) or injury (traumatic amputation). Patients with minor distal amputations typically do not require special shoes. When all digits have been amputated, a forefoot filler orthosis may be used with a commercial shoe. For more extensive partial-foot amputations (e.g., mid-level Trans metatarsal, Chopart's amputation), a prosthetic may be needed consisting of a conventional shoe with an ankle-foot orthosis (AFO), brace and a forefoot filler. A

custom-fitted or custom-molded foot orthosis may be used as a replacement or substitute for missing parts of the foot (e.g., due to amputation) and when it is necessary for the alleviation or correction of illness, injury or congenital defect.

Neurologic and Neuromuscular Conditions: Certain neurologic and muscle control conditions such as stroke, neoplasms, hemiplegia, cerebral palsy, myelomeningocele and atrophic or dystrophic conditions may produce lower extremity spasticity or hyperactivity of muscles, hypotonicity of certain muscles and neuromuscular imbalances. Pes cavus, a foot deformity characterized by a high medial longitudinal arch, typically results from an underlying neurological problem (e.g., Charcot-Marie-Tooth disease, poliomyelitis, Friedreich's ataxia). This condition results in abnormal pressure loading on the plantar surface of the foot resulting in foot pain, heel pain, metatarsalgia, ankle instability, in addition to weakness and fatigue from the neuromuscular disease. Gait functioning, balance and foot/ankle positioning may be impacted as a result of neuromuscular or neurologic conditions. Custom-fitted and custom-molded foot orthoses and ankle-foot orthoses (AFOs) are used in ambulatory patients to control or correct foot joints, counteract internal deforming forces, compensate for weakness, correct or eliminate pathologic positioning, improve balance, improve gait functioning and reduce excessive plantar flexion.

Plantar Fasciitis (Heel Pain Syndrome): Plantar fasciitis is an inflammation of the heel of the foot typically resulting from trauma to the deep tissue of the foot (i.e., plantar fascia). Conditions involving heel pain are referred to by many names, including heel spurs, heel spur syndrome, plantar fasciitis, heel pain syndrome, painful-heel syndrome, calcaneodynia, subcalcaneal bursitis and stone bruise. Treatment options typically include stretching exercises, taping, strapping, injection therapy, nonsteroidal anti-inflammatory medications, walking splints, night splints, casting, reduced activity and physical therapy. There is some consensus among authors that orthoses are effective for treating this condition. The orthotic device utilized may be an over-the-counter device, prefabricated, or customized. The orthosis reduces symptoms associated with plantar fasciitis by reducing strain in the fascia, by cushioning and elevating the heel and/or providing medial arch support during standing and ambulation. Prefabricated orthoses, which include heel lifts, heel protectors, heel cushions and dynamic insoles, have been shown to be adequate for the majority of patients with various heel pain syndromes. Custom-molded foot orthoses are used when more conservative measures fail (Landorf, et al., 2006; Fink and Mizel, 2001; Pfeffer, et al., 1999). In addition, prefabricated posterior night splints may also be used for treatment of plantar fasciitis and Achilles tendonitis. Surgery should be considered only after all other forms of treatment have failed.

Evidence in the published scientific literature does not demonstrate a clear advantage of one treatment over another. Experts generally recommend that conservative therapy should be tried first, and over-the-counter arch supports and heel pads should be tried for most patients prior to the use of custom-fabricated devices.

Literature Review: Overall, the clinical effectiveness of foot orthoses is debatable. Many studies have used various combinations of treatments and various types of materials, making it difficult to draw conclusions regarding the unique effectiveness of each treatment. There is some evidence in the published, scientific, peer-reviewed literature and clinical practice guidelines to suggest that custom-fitted and custom-fabricated foot orthoses are at least as effective as prefabricated orthoses for the treatment of heel-pain syndromes and related conditions. In cases where prefabricated foot orthoses provide inadequate relief or are contraindicated, custom-fitted or custom-molded orthoses may be appropriate.

Few studies directly compare the use of prefabricated devices to custom-fabricated devices. Some authors have reported that when comparing effectiveness of custom foot orthoses with prefabricated devices there is either no difference or that prefabricated devices performed better than custom devices (Landorf et al., 2004; Cole, et al., 2005; Landorf, et al., 2006). Pre-fabricated and custom fabricated have been shown to reduce rearfoot pressure in subjects with plantar fasciitis (Chia, et al., 2009) suggesting clinical utility. A Cochrane review by Hawke et al. (2008) found custom-made foot orthoses to be a safe intervention in all studies, but it was unclear if these orthoses were effective for plantar fasciitis. Earlier Cochrane reviews (2003, 2004) stated the evidence to support effectiveness of various treatments for plantar pain, including foot orthoses, has not been established in comparative trials. Roos et al. (2006) studied the effects of a custom-fitted foot orthoses and night splints, alone or combined, in a prospective randomized trial and reported that foot orthoses and anterior night splints were effective both short-term (i.e., three months) and long-term (i.e., one-year) in treating pain from plantar fasciitis.

Practice guidelines have been published that support the use of foot orthoses in the treatment for plantar fasciitis. The Diagnosis and Treatment of Heel Pain practice guideline, developed by the Clinical Practice Guideline Heel Pain Panel of the American College of Foot and Ankle Surgeons (2001), recommends the use of custom orthotic devices (especially in the biomechanically malaligned patients), the use of night splints, corticosteroid injections and cast immobilization as second line therapy when initial treatment measures fail. A consensus statement contained within a practice guideline developed by the American College of Foot and Ankle Orthopedics and Medicine (2004) for the use of prescription custom foot orthoses, recommends prescription custom fabricated orthoses for the treatment of plantar fasciitis, especially in cases where temporary or over-the-counter arch supports provide inadequate relief.”

Foot orthoses with magnetic foil (i.e., magnetic insoles) have been considered by some authors as a treatment for plantar fasciitis, although the available data regarding efficacy is limited and questionable (Roxas, 2005; Stuber Kristmanson, 2006). The theory behind magnet therapy is that magnetic fields create an electrical current that interrupts the transmission of pain signals in the central nervous system as well as increasing blood flow to an area, boosting the flow of oxygen and other nutrients, ultimately reducing pain and swelling. Winemiller et al. (2003) conducted a prospective, randomized, double-blind, placebo-controlled study comparing cushioned insoles with magnetic foil cushioned insoles and concluded that magnetic foil did not provide any additional benefit compared to nonmagnetic insoles.

Foot Deformities: Some foot deformities such as flatfoot (pes planus) and bunions (hallux valgus) may cause malalignment of the feet and/or ankles and pathologic foot positioning, thereby causing impaired gait, balance and pain. Flatfoot deformity may occur in both pediatric and adult populations. The degree of flatfoot is subjective, and treatment decisions are usually based on the presence or absence of pain, Achilles contracture, or accessory navicular (Jackson and Stricker, 2003). It has been proposed that orthotic devices can relieve symptoms by providing structural support to the weakened foot, by limiting the amount of abnormal pronation, or by allowing more efficient locomotion (Noble, 2001). The American College of Foot and Ankle Surgeons (ACFAS) Clinical Practice Guidelines (Lee et al., 2004; Harris et al., 2004; Vanore et al., 2003) describe the following:

- Pediatric flatfoot can be further divided as flexible or rigid. Flexible flatfoot is characterized by a visible arch during nonweightbearing and flattening of the arch on stance. Rigid flatfoot is characterized by a stiff flattened arch on and off weightbearing. Both conditions may or may not be symptomatic. Flexible asymptomatic flatfoot requires no treatment. Symptomatic flexible flatfoot may require treatment with conservative measures such as activity modification, orthoses, stretching exercises and nonsteroidal medications. Surgery may be required if conservative management is unsuccessful. Treatments for conditions that result in rigid flatfoot often involve the addition of shoe modifications, casting or braces, and custom orthoses. It has been suggested that early treatment of flatfoot in a child will promote better support and fewer symptoms; however, it does not correct the deformity.
- Adult flatfoot is a more complex condition resulting in various symptoms and degrees of deformity. Adult flexible flatfoot is typically a progression of a pediatric condition. If asymptomatic, observation and patient education is sufficient. If symptomatic, initial treatment is the same as for pediatric conditions. In some cases, adult flatfoot may be the result of a ruptured posterior tibial tendon (i.e., acquired adult flatfoot), and, depending on the stage of progression, may be flexible or rigid. The tendon helps to support the arch, and helps to lift the heel off the ground when walking. If the tendon becomes inflamed, over-stretched or torn, it may cause pain and lead to loss of the inner arch. Treatment consists of rest, nonsteroidal anti-inflammatory medications, and immobilization of the foot for 6–8 weeks. Heel wedges and arch supports may be recommended, in addition to custom-fabricated ankle foot orthosis or supports.
- Hallux valgus is a deformity of the first metatarsophalangeal joint and is very common. Hallux valgus is a lateral deviation of the great toe towards the midline of the foot. It is often associated with bunion formation. A bunion is an inflammation and thickening of the first metatarsal joint of the great toe. The treatment is dependent on symptoms, and may include analgesics, shoe modifications and/or activity modification. The effectiveness of orthotic devices (prefabricated or custom-fabricated) has not been proven in the scientific literature (ACFAS, 2004), although some patients do obtain relief. .

Hallux rigidus, also referred to as hallux limitus, is a painful flexion deformity of the great toe with limitation of motion of the metatarsophalangeal joint. It is considered an osteoarthritis condition which may occur in

adolescents, adults, and may also be associated with previous trauma. Symptoms are related to degenerative arthritis of the great toe joint and typically include pain and/or joint stiffness. Nonsurgical methods of treatment such as activity modification, nonsteroidal anti-inflammatory medications and the use of in-shoe orthotics or shoe modifications are usually successful for most individuals. Biomechanical treatment is an integral component of treatment and includes shoe modifications with stiff or rocker-bottom soles, or extra-depth shoes may be helpful.

Foot orthoses are often prescribed for treatment for arthritic conditions, including rheumatoid arthritis. Arthritis can result from degenerative joint disease, injury or trauma and cause foot pain and deformity. Conservative treatment goals include relief of pain, accommodation or prevention of deformity, and improvement of function. Taping, shoe modifications and orthotic devices are often used as treatment for forefoot arthritis, while custom orthotic devices may provide support and relieve symptoms for midfoot and hindfoot instability (Abdo and Iorio, 1994). Initial treatment involves nonsteroidal anti-inflammatory drugs combined with prefabricated orthotic devices to enhance stability and decrease pain. Custom-molded orthotics combined with range-of-motion exercises and stretching techniques have been recommended when initial modalities fail (Frontera, 2002). Powell et al. (2005) reported in a randomized clinical trial (n=40) that custom-made semirigid foot orthotics improved pain reduction, speed of ambulation, self-rated activity and functional ability levels when compared with prefabricated off-the-shelf shoe inserts or supportive athletic shoes worn alone.

Recommended use and clinical effectiveness of foot orthotics for the treatment of foot deformities is widely debated in the literature. For most conditions, evidence in the published, peer-reviewed, scientific literature does not demonstrate that custom foot orthoses are equal or superior to standard, properly fitted, commercially available footwear or over-the-counter prefabricated supports for patients with various types of congenital or acquired foot deformities. Some authors recommend custom-fabricated functional orthosis for treatment of various foot conditions (Noble, 2001), and others recommend those that consist of firmer, more rigid materials posted medially to help minimize pronation (Nawoczinski, 2004). Other authors have suggested orthotics such as the University of California Biomechanics Laboratory (UCBL) brace, molded ankle-foot orthoses, articulated molded ankle-foot orthoses, or a Marzano brace for the treatment of conditions such as flexible flatfoot (Wilder and Sethi, 2004). Nonetheless, the use of custom orthopedic shoes and inserts does not influence the course of flexible flatfeet in children (Wenger, et al., 1989).

Evidence published in textbooks and clinical practice guidelines also suggests commercially available, properly fitted footwear and over-the-counter, prefabricated orthotic devices are adequate for treatment of painful foot conditions for most patients. However, there may be circumstances when custom-fabricated foot orthoses are needed for use either in commercial footwear or in specialized orthopedic shoes to control biomechanical function and relieve pain. Significant foot deformities may require modification of footwear in order to maintain normal alignment, gait patterns and balance. In cases where prefabricated foot orthoses are contraindicated or provide inadequate pain relief, custom-fitted or custom-molded orthoses may be appropriate.

Ankle Orthoses

An ankle orthosis is a type of orthotic device used to treat acute ankle injuries such as a sprain, for rehabilitation after the initial injury and to prevent re-injury of the ankle. They are also used to treat chronically unstable ankles. Ankle orthotic device options include lightweight sports plastics/Velcro models, hinged devices, lace-up devices, neoprene sleeves, ankle wraps and taping, braces, various types of casts, stabilizing shoes and air stirrups.

Ankle-Foot Orthoses (AFO)

An AFO extends well above the ankle to the top of the calf. It requires fastening at the lower leg, just above the ankle. This device may be considered medically necessary for ambulatory patients with weakness or deformity of the foot and ankle, which also require stabilization for medical reasons and when the patient has the potential to benefit functionally from use of the device. Commonly, AFOs are used to treat disorders including but not limited to ankle dorsiflexion (upward motion), plantar flexion (downward motion), inversion and eversion (turning inward or outward), spastic diplegia due to cerebral palsy, lower motor neuron weakness due to poliomyelitis and spastic hemiplegia in cerebral infarction. HCPCS codes representing AFO devices are L1900–L1990, L2106–L2116, L4350, L4360, and L4386.

Knee-Ankle-Foot Orthoses (KAFO)

A KAFO is an AFO with metal uprights, a mechanical knee joint and two thigh bands. KAFOs may be medically necessary for ambulatory patients who meet criteria for an ankle-foot orthosis, and who also require additional support to the knee for stability. HCPCS codes representing KAFOs are L2000–L2039, L2126–L2136, and L4370.

L-code additions to AFOs or KAFOs (L2180–L2550, L2750–L2830) are considered not medically necessary if either the base orthosis is not medically necessary or the specific addition is not medically necessary.

AFOs and KAFOs used for ambulatory patients for the treatment of edema and/or for the prevention or treatment of pressure ulcers are considered not medically necessary because they do not meet the definition of a brace and are not used to treat a weakness or deformity that requires stabilization. In addition, walking boots (L4360 and L4386) are AFOs that may be used to relieve pressure on the sole of the foot or used for patients with foot ulcers and are considered not medically necessary for those conditions. Walking boots may be considered medically necessary when used to treat orthopedic conditions or postoperatively for orthopedic surgery.

Ankle flexion contracture is a condition where the muscles and/or tendons that plantarflex the ankle are shortened, resulting in an inability to bring the ankle to 0° by passive range of motion. At 0° flexion, the ankle is perpendicular to the lower leg. An ankle-contraction splint is a prefabricated ankle-foot orthosis that has all of the following characteristics:

- designed to accommodate an ankle with a plantar flexion contracture of up to 45°
- applies dorsiflexion force up to the ankle
- for use by a patient who is nonambulatory
- has a soft interface

Foot drop is a condition where there is a weakness and/or lack of use of the muscles that dorsiflex the ankle, but there is the ability to bring the ankle to 0° by passive range of motion. A foot drop splint/recumbent positioning device is a prefabricated ankle-foot orthosis that has all of the following characteristics:

- designed to maintain the foot at a fixed position of 0° (i.e., perpendicular to the lower leg)
- not designed to accommodate an ankle with a plantar flexion contracture
- for use by a patient who is nonambulatory
- has a soft interface

An ankle-foot orthosis used in nonambulatory patients may be either an ankle contracture splint, night splint or a foot drop splint. Ankle contracture splints (L4396) are considered not medically necessary when used solely for the prevention or treatment of a heel pressure ulcer. Foot drop splints (L4398) and/or replacement interface (L4394) are recumbent positioning devices and are considered not medically necessary in a nonambulatory patient or when used solely for the prevention or treatment of heel pressure ulcers. These types of devices are not used to support a weak or deformed body part, or to restrict or eliminate motion in a diseased or injured part of the body (i.e., they do not meet the definition of a brace).

If an AFO is to be used for a nonambulatory patient for the treatment of plantar flexion contracture, the pretreatment passive range of motion must be measured with a goniometer and documented in the medical record. There must be documentation of an appropriate stretching program carried out by the professional staff (in a nursing facility) or caregiver (at home). An ankle-contraction splint is considered not medically necessary for the treatment of a fixed contracture and/or in patients who demonstrate foot drop without an ankle-flexion contracture. The effectiveness of components of the ankle-contraction splint used to correct positioning of the knee or hip is not well-established in the peer-reviewed literature.

Stance Control Orthoses

A stance control orthosis is an orthotic knee joint or custom-fabricated KAFO that allows swing-phase knee flexion. The knee joint locks when weight-bearing to provide stance phase stability and, when not weighted, it unlocks to allow a swinging motion of the knee. It is proposed that the stance control components allow the patient to swing their impaired limb with sufficient ground clearance to provide a more normal gait. While there are no specific patient criteria, it is intended for use in patients with lower extremity weakness and who

demonstrate some control of hip muscles. Candidates who may benefit from this type of device typically have conditions such as polio, post-polio syndrome, spinal cord injuries, multiple sclerosis, stroke or trauma.

These devices may be mechanical or electronic. The Stance Control Orthotic Knee Joint (Horton SCOKJ) and the Free Walk Stance Control Knee Ankle System (Otto Bock) are currently available in the United States and function as mechanical devices. The Horton SCOKJ is a knee joint that is fabricated into a custom KAFO. This device has a switch allowing the patient to select an automatic mode for stance control, an unlocked position for motion associated with free-swinging KAFO, and a locked extension for use with climbing. The Free Walk (Otto Bock) is an entire KAFO system, a single-upright KAFO with a foot-plate design. This device has an automatic lock initiated by knee extension. An electronic device, the Becker 9001 E-Knee is one that can be programmed to lock at any degree of flexion and unlock in response to various conditions. It is a computer-controlled, foot-force activated, electromechanical orthotic knee joint. The Sensor Walk™ is another electronic stance control KAFO which received approval from the FDA 510(k) process in May 2006. The Sensor Walk is a microprocessor controlled KAFO proposed to achieve a safer, more physiologically correct gait.

The available evidence in the published, peer-reviewed scientific literature has not shown conclusively that stance control orthotic devices are superior to standard knee-ankle-foot orthoses. Most of the studies that support improvement of gait are in the form of small case reports (Yakamovich et al., 2006; Herbert and Liggins, 2005) and case series (Irby, et al., 2005); therefore, the ability to generalize results is limited. There are no studies evaluating the degenerative changes in the contralateral limb and lower back with use of a standard device compared to use of a stance control orthotic to support long-term outcomes. Further research is needed to determine whether a stance control orthosis is an effective alternative to a standard locked KAFO and to further define patient selection criteria.

University of California Berkeley Laboratory (UCBL) Orthosis (HCPCS L3000)

This orthosis is a variant of the traditional prefabricated arch support and was originally designed to maintain a flexible, paralytic valgus foot deformity in the corrected position. This orthosis is cast in a semi-weight-bearing position. Some authors recommend the device to treat flatfoot, plantar fasciitis, calcaneal spurs, posterior tibial tendon dysfunction and rheumatoid arthritis.

Shoes

Impaired circulation and decreased peripheral sensation of the lower extremities may contribute to the development of various foot conditions that are likely to result in ulceration or amputation. According to the American Diabetes Association (ADA), foot-related conditions that are associated with an increased risk of amputation include the following:

- peripheral neuropathy with loss of protective sensation
- altered biomechanics (in the presence of neuropathy)
- evidence of increased pressure
- bony deformity
- peripheral vascular disease
- a history of ulcers or amputation
- severe nail pathology

Improper footwear may contribute to these conditions. In contrast to standard shoes (basic shoe), therapeutic shoes have additional depth and may be used to accommodate foot deformities. In general, therapeutic shoes may be considered medically necessary for the treatment of some foot conditions, are accommodative or functional, and are fitted and furnished by a specially trained health professional (e.g., podiatrist, orthotist, prosthetist) or certified pedorthotist. Shoe selection is based primarily on the foot condition or related disease, the shape of the foot, and the individual's daily activities (Janisse and Janisse, 2008). Standard shoes (basic shoes) purchased over-the-counter are not considered therapeutic shoes.

Appropriate management of individuals with diabetes mellitus and other foot-related conditions includes the selection of appropriate footwear. According to the ADA, diabetic individuals with neuropathy or evidence of plantar pressure may be adequately managed with a well-fitted walking shoe or athletic shoe; those with bony deformities (e.g., hammertoes, prominent metatarsal heads, bunions) may require extra-wide shoes or depth shoes; those with extreme bony deformities (e.g., Charcot foot) who cannot be accommodated with commercial

therapeutic footwear may require custom-molded shoes (ADA, 2007). Early management is important for prevention or delay of ulceration and/or amputation.

Shoes Types and Accessories: Therapeutic shoes that may be considered medically necessary for a person with systemic conditions that involve impaired circulation and/or loss of protective sensation, including diabetes mellitus, include a depth shoe (HCPCS code A5500) or a custom-molded shoe (HCPCS code A5501), and may or may not have an internally seamless toe. A depth shoe is defined as follows:

- has a full length, heel-to toe filler that when removed provides a minimum of 3/16" of additional depth used to accommodate custom-molded or customized inserts
- is made from leather or other suitable material of equal quality
- has some form of closure (e.g., velcro, lace or zipper)
- is available in full and half sizes with a minimum of three width so that the sole is graded to the size and width of the upper portions of the shoe according to the American standard last sizing schedule or its equivalent. (The American last sizing schedule is the numerical shoe sizing system used for shoes in the United States.)

A custom-molded shoe is defined as follows:

- is constructed over a positive model or mold of an individual's foot
- is made of leather or other suitable material of equal quality
- has removable inserts which can be altered or replaced as the individual's condition warrants
- has some form of shoe closure (lace, velcro, zipper).

Therapeutic shoe inserts (HCPCS A5512, A5513) and/or modifications (HCPCS codes A5503, A5504, A5505, A5506, and A5507) may be considered medically necessary and are often required for correct fitting of the shoe. Inserts are total contact (continuous physical contact with weight-bearing portion of the foot) multiple density removable inlays that are directly molded to the plantar surface of the individual's foot or a model of the foot. Modifications of depth or custom-molded shoes include but are not limited to:

- rigid rocker bottoms
- roller bottoms
- wedges
- metatarsal bars
- offset heels
- flared heels

Deluxe features (HCPCS codes A5508) such as special colors, special leathers, and styles do not contribute to the accommodative or therapeutic function of the shoe and are not considered medically necessary.

Inlays (i.e., inserts) that reflect compression molding to the individual's foot over time through heat and pressure generated by wearing a shoe with the insert present (HCPCS code A5510), without external heat sources, do not offer total contact and are not considered medically necessary.

Other Orthoses and Accessories

Orthoses and accessories that are used for participation in sports, to improve athletic performance, that are used to prevent injury in an otherwise uninjured body part, and that are used in conjunction with the device (e.g., socks) are considered not medically necessary.

Identical, spare orthoses purchased only for the patient's convenience are considered not medically necessary. Additionally, one orthotic per foot is considered appropriate; separate orthotic devices for additional pairs of shoes are not considered medically necessary.

Summary

Lower limb orthoses may be medically necessary to support or aid in the treatment of illness or injury. Some clinical studies evaluating the clinical effectiveness of certain lower limb orthoses provide strong support of efficacy, and others do not. Reported patient outcomes vary, are often subjective, and include patient

satisfaction, relief of pain, correction of deformity and correct positioning and motion. Furthermore, for individuals with impaired circulation and/or decreased peripheral sensation— conditions that place an individual at risk for lower extremity ulceration and amputation—proper foot care, including therapeutic shoes, is strongly recommended.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary only when coverage is available for the specific item. Benefit exclusions and limitations may apply. Some of these items are specifically excluded under many plans and therefore generally not covered:

CPT ^{®*} Codes	Description
29799 [†]	Unlisted procedures, casting or strapping

[†]**Note:** Covered when medically necessary and when used to report bilateral casting or strapping for custom-fabricated lower limb orthoses.

HCPCS Codes	Description
A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multi-density insert(s), per shoe
A5501	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe
A5503	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with roller or rigid rocker bottom, per shoe
A5504	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with wedge(s), per shoe
A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with metatarsal bar, per shoe
A5506	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with off-set heel(s), per shoe
A5507	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of shore a 35 durometer or 3/16 inch material of shore a 40 durometer (or higher), prefabricated, each
A5513	For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer or higher, includes arch filler and other shaping material, custom fabricated, each
L1900	AFO, spring wire, dorsiflexion assist calf band, custom fabricated
L1902	AFO, ankle gauntlet, prefabricated, includes fitting and adjustment
L1904	AFO, molded ankle gauntlet, custom fabricated
L1906	AFO, multiligamentous ankle support, prefabricated, includes fitting and adjustment
L1907	AFO, supramalleolar with straps, with or without interface/pads, custom fabricated
L1910	AFO, posterior, single bar, clasp attachment to shoe counter, prefabricated, includes fitting and adjustment
L1920	AFO, single upright with static or adjustable stop (Phelps or Perlstein type),

	custom fabricated
L1930	AFO, plastic or other material, prefabricated, includes fitting and adjustment
L1932	AFO, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment
L1940	AFO, plastic or other material, custom-fabricated
L1945	AFO, molded to patient model, plastic, rigid anterior tibial section (floor reaction), custom fabricated
L1950	AFO, spiral, (Institute of Rehabilitative Medicine type), plastic, custom-fabricated
L1951	AFO, spiral, (Institute of Rehabilitative Medicine type), plastic or other material, prefabricated, includes fitting and adjustment
L1960	AFO, posterior solid ankle, plastic, custom fabricated
L1970	AFO, plastic, with ankle joint, custom fabricated
L1971	AFO, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment
L1980	AFO, single upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar "BK" orthosis), custom fabricated
L1990	AFO, double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (double bar "BK" orthosis), custom fabricated
L2000	KAFO, single upright, free knee, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar "AK" orthosis), custom fabricated
L2010	KAFO, single upright, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar "AK" orthosis), without knee joint, custom fabricated
L2020	KAFO, double upright, free knee, free ankle, solid stirrup, thigh and calf bands/cuffs (double bar "AK" orthosis), custom fabricated
L2030	KAFO, double upright, free ankle, solid stirrup, thigh and calf bands/cuffs, (double bar "AK" orthosis), without knee joint, custom fabricated
L2034	KAFO, full plastic, single upright, with or without free motion knee, medial lateral rotation control, with or without free motion ankle, custom fabricated
L2035	Knee ankle foot orthosis, full plastic, static (pediatric size), without free motion ankle, prefabricated, includes fitting and adjustment
L2036	Knee ankle foot orthosis, full plastic, double upright, free knee, with or without free motion ankle, custom fabricated
L2037	Knee ankle foot orthosis, full plastic, single upright, free knee, with or without free motion ankle, custom fabricated
L2038	Knee ankle foot orthosis, full plastic, without knee joint, multi-axis ankle, custom fabricated
L2106	AFO, fracture orthosis, tibial fracture cast orthosis, thermoplastic type casting material, custom fabricated
L2108	AFO, fracture orthosis, tibial fracture cast orthosis, custom fabricated
L2112	AFO, fracture orthosis, tibial fracture orthosis, soft, prefabricated, includes fitting and adjustment
L2114	AFO, fracture orthosis, tibial fracture orthosis, semi-rigid, prefabricated, includes fitting and adjustment
L2116	AFO, fracture orthosis, tibial fracture orthosis, rigid, prefabricated, includes fitting and adjustment
L2126	KAFO, fracture orthosis, femoral fracture cast orthosis, thermoplastic type casting material, custom fabricated
L2128	KAFO, fracture orthosis, femoral fracture cast orthosis, custom fabricated
L2132	KAFO, fracture orthosis, femoral fracture cast orthosis, soft, prefabricated, includes fitting and adjustment
L2134	KAFO, fracture orthosis, femoral fracture cast orthosis, semi-rigid, prefabricated, includes fitting and adjustment
L2136	KAFO, fracture orthosis, femoral fracture cast orthosis, rigid, prefabricated, includes fitting and adjustment
L2180	Addition to lower extremity fracture orthosis, plastic shoe insert with ankle joints
L2182	Addition to lower extremity fracture orthosis, drop lock knee joint

L2184	Addition to lower extremity fracture orthosis, limited motion knee joint
L2186	Addition to lower extremity fracture orthosis, adjustable motion knee joint, Lerman type
L2188	Addition to lower extremity fracture orthosis, quadrilateral brim
L2190	Addition to lower extremity fracture orthosis, waist belt
L2192	Addition to lower extremity fracture orthosis, hip joint, pelvic band, thigh flange, and pelvic belt
L2200	Addition to lower extremity, limited ankle motion, each joint
L2210	Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint
L2220	Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint
L2230	Addition to lower extremity, split flat caliper stirrups and plate attachment
L2232	Addition to lower extremity orthosis, rocker bottom for total contact ankle foot orthosis, for custom fabricated orthosis only
L2240	Addition to lower extremity, round caliper and plate attachment
L2250	Addition to lower extremity, foot plate, molded to patient model, stirrup attachment
L2260	Addition to lower extremity, reinforced solid stirrup (Scott-Craig type)
L2265	Addition to lower extremity, long tongue stirrup
L2270	Addition to lower extremity, varus/valgus correction ("T") strap, padded/lined or malleolus pad
L2275	Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined
L2280	Addition to lower extremity, molded inner boot
L2300	Addition to lower extremity, abduction bar (bilateral hip involvement), jointed, adjustable
L2310	Addition to lower extremity, abduction bar, straight
L2320	Addition to lower extremity, non-molded lacer, for custom fabricated orthosis only
L2330	Addition to lower extremity, lacer molded to Patient model, for custom fabricated orthosis only
L2335	Addition to lower extremity, anterior swing band
L2340	Addition to lower extremity, pretibial shell, molded to patient model
L2350	Addition to lower extremity, prosthetic type, (BK) socket, molded to patient model, (used for "PTB," "AFO" orthoses)
L2360	Addition to lower extremity, extended steel shank
L2370	Addition to lower extremity, patten bottom
L2375	Addition to lower extremity, torsion control, ankle joint and half solid stirrup
L2380	Addition to lower extremity, torsion control, straight knee joint, each joint
L2385	Addition to lower extremity, straight knee joint, heavy duty, each joint
L2387	Addition to lower extremity, polycentric knee joint, for custom fabricated knee ankle foot orthosis, each joint
L2390	Addition to lower extremity, offset knee joint, each joint
L2395	Addition to lower extremity, offset knee joint, heavy duty, each joint
L2397	Addition to lower extremity orthosis, suspension sleeve
L2405	Addition to knee joint, lock; drop, stance or swing phase, each joint
L2415	Addition to knee lock with integrated release mechanism (bail, cable, or equal), any material, each joint
L2425	Addition to knee joint, disc or dial lock for adjustable knee flexion, each joint
L2430	Addition to knee joint, ratchet lock for active and progressive knee extension, each joint
L2492	Addition to knee joint, lift loop for drop lock ring
L2500	Addition to lower extremity, thigh/weight bearing, gluteal/ischial weight bearing, ring
L2510	Addition to lower extremity, thigh/weight bearing, quadri-lateral brim, molded to patient model
L2520	Addition to lower extremity, thigh/weight bearing, quadri-lateral brim, custom

	fitted
L2525	Addition to lower extremity, thigh/weight bearing, ischial containment/narrow m-l brim molded to patient model
L2526	Addition to lower extremity, thigh/weight bearing, ischial containment/narrow m-l brim, custom fitted
L2530	Addition to lower extremity, thigh/weight bearing, lacer, nonmolded
L2540	Addition to lower extremity, thigh/weight bearing, lacer, molded to patient model
L2550	Addition to lower extremity, thigh/weight bearing, high roll cuff
L2750	Addition to lower extremity orthosis, plating chrome or nickel, per bar
L2755	Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only
L2760	Addition to lower extremity orthosis, extension, per extension, per bar (for lineal adjustment for growth)
L2768	Orthotic side bar disconnect device, per bar
L2780	Addition to lower extremity orthosis, noncorrosive finish, per bar
L2785	Addition to lower extremity orthosis, drop lock retainer, each
L2795	Addition to lower extremity orthosis, knee control, full kneecap
L2800	Addition to lower extremity orthosis, knee control, knee cap, medial or lateral pull, for Use with custom fabricated orthosis only
L2810	Addition to lower extremity orthosis, knee control, condylar pad
L2820	Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
L2830	Addition to lower extremity orthosis, soft interface for molded plastic, above knee section
L2861	Addition to lower extremity joint, knee or ankle, concentric adjustable torsion style mechanism for custom fabricated orthotics only, each
L3000	Foot insert, removable, molded to patient model, "UCB" type, Berkeley shell, each
L3001	Foot insert, removable, molded to patient model, Spenco, each
L3002	Foot insert, removable, molded to patient model, Plastazote or equal, each
L3003	Foot insert, removable, molded to patient model, silicone gel, each
L3010	Foot insert, removable, molded to patient model, longitudinal arch support, each
L3020	Foot insert, removable, molded to patient model, longitudinal/metatarsal support, each
L3030	Foot insert, removable, formed to patient foot, each
L3031	Foot, insert/plate, removable, addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, each
L4002	Replacement strap, any orthosis, includes all components, any length, any type
L4010	Replace trilateral socket brim
L4205	Repair of orthotic device, labor component, per 15 minutes
L4210	Repair of orthotic device, repair or replace minor parts
L4350	Ankle control orthosis, stirrup style, rigid, includes any type interface (e.g., pneumatic, gel), prefabricated, includes fitting and adjustment
L4360	Walking boot, pneumatic, with or without joints, with or without interface material, prefabricated, includes fitting and adjustment
L4370	Pneumatic full leg splint, prefabricated, includes fitting and adjustment
L4386	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated, includes fitting and adjustment
L4392	Replacement soft interface material, static AFO
L4396	Static or dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated, includes fitting and adjustment
L5816	Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock
S0395	Impression casting of a foot performed by a practitioner other than manufacturer of the orthotic

ICD-9-CM Diagnosis Codes	Description
250.60-250.73	Diabetes with neurological manifestations or peripheral circulatory manifestations, type I, type II or unspecified type, not stated as uncontrolled
342.10	Spastic hemiplegia affecting unspecified side
342.11	Spastic hemiplegia affecting dominant side
342.12	Spastic hemiplegia affecting nondominant side
343.0 - 343.9	Infantile cerebral palsy
356.0	Hereditary peripheral neuropathy
443.89	Other peripheral vascular disease
443.9	Unspecified peripheral vascular disease
728.71	Plantar fascial fibromatosis
736.70-736.76	Deformity of ankle and foot, acquired
741.00	Spina bifida with hydrocephalus, unspecified region
741.93	Spina bifida without mention of hydrocephalus, lumbar region
754.50-754.71	Deformity of ankle,/foot, congenital
755.30 - 755.39	Congenital reduction deformities of lower limb
755.64 - 755.69	Congenital anomaly of lower limb
824.0 - 824.9	Fracture of Ankle
845.00 - 845.09	Ankle sprain and strain
	Multiple/Varied

Experimental/Investigational/Unproven/Not Covered:

HCPSC Codes	Description
A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe
A5510	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe
L2005 ^{††}	Knee-ankle-foot orthosis, any material, single or double upright, stance control, automatic lock and swing phase release, mechanical activation, includes ankle joint, any type, custom fabricated.
L2840	Addition to lower extremity orthosis, tibial length sock, fracture or equal, each
L2850	Addition to lower extremity orthosis, femoral length sock, fracture or equal, each
L4394	Replacement soft interface material, foot drop splint
L4398	Foot drop splint, recumbent positioning device, prefabricated, includes fitting and adjustment

^{††}**Note:** Experimental, investigational or unproven and not covered when used to report a mechanical or electronic stance control orthosis.

ICD-9-CM Diagnosis Codes	Description
735.0 ^{†††}	Hallux valgus (acquired)
735.2 ^{†††}	Hallux rigidus
	Multiple/Varied

††† **Note: Experimental, investigational or unproven and not covered for all custom-fabricated foot orthoses for the treatment of hallux valgus or hallux rigidus foot deformity.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	8/15/2008	0150	Lower Limb Orthoses and Therapeutic Shoes

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.